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| APPLICATION NO.                                                                      | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------------------------------------------------------|-----------------|----------------------|---------------------|------------------|
| 09/894,845                                                                           | 06/27/2001      | Xavier Paliard       | 1681.002            | 3705             |
| Managla I illia                                                                      | 7590 02/05/2008 |                      | EXAMINER            |                  |
| Marcella Lillis Intellectual Property - R440 P.O. Box 8097 Emeryville, CA 94662-8097 |                 |                      | ANGELL, JON E       |                  |
|                                                                                      |                 |                      | ART UNIT            | PAPER NUMBER     |
| . 2,, 2,                                                                             |                 |                      | 1635                |                  |
|                                                                                      |                 |                      |                     |                  |
|                                                                                      |                 |                      | MAIL DATE           | DELIVERY MODE    |
|                                                                                      |                 |                      | 02/05/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Application No.                                                                                                                                              | Applicant(s)                                                    |  |  |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|--|--|--|
| t                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 09/894,845                                                                                                                                                   | PALIARD, XAVIER                                                 |  |  |  |
| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Examiner                                                                                                                                                     | Art Unit                                                        |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | J. Eric Angell                                                                                                                                               | 1635                                                            |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                              |                                                                 |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).                                                                                         | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timused and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | I. the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                              |                                                                 |  |  |  |
| <ol> <li>Responsive to communication(s) filed on <u>01 Not</u></li> <li>This action is FINAL.</li> <li>Since this application is in condition for allower closed in accordance with the practice under Exercise.</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                        | action is non-final.  nce except for formal matters, pro                                                                                                     |                                                                 |  |  |  |
| Disposition of Claims                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                              |                                                                 |  |  |  |
| 4) ⊠ Claim(s) <u>1-3,6,7,10-12,15-21,41 and 43-46</u> is/a 4a) Of the above claim(s) is/are withdraw 5) □ Claim(s) is/are allowed. 6) □ Claim(s) is/are rejected. 7) □ Claim(s) is/are objected to. 8) ⊠ Claim(s) <u>1-3, 6, 7, 10-12, 15-21, 41 and 43-46</u>                                                                                                                                                                                                                                                                                                                                                     | vn from consideration.                                                                                                                                       | election requirement.                                           |  |  |  |
| Application Papers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                              |                                                                 |  |  |  |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine                                                                                                                                                                                                                                                                                                                                                  | epted or b) objected to by the bed drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj                                              | e 37 CFR 1.85(a).<br>jected to. See 37 CFR 1.121(d).            |  |  |  |
| Priority under 35 U.S.C. § 119                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                              |                                                                 |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |                                                                                                                                                              |                                                                 |  |  |  |
| Attachment(s)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | _                                                                                                                                                            |                                                                 |  |  |  |
| Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date                                                                                                                                                                                                                                                                                                                                                                                                                                    | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:                                                                                   | ate                                                             |  |  |  |

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## **DETAILED ACTION**

## Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/1/2007 has been entered.

Claims 1-3, 6, 7, 10-12, 15-21, 41 and 43-46 are currently pending and are addressed herein.

## Election/Restrictions

It is noted that the amendment filed 11/1/2007 added new claims 43-46 which encompass patentably distinct species which were not previously present in the claims. Therefore, the amendment necessitates a species election requirement.

Claims 1-3, 6, 7, 10-12, 15-21, 41 are generic to the following disclosed patentably distinct species:

- (1) A nucleic acid which that directs liver specific expression of an HCV immunogen wherein the nucleic acid comprises a liver specific promoter wherein the liver specific promoter is an alpha-1 anti-trypsin promoter (claims 43 and 44); and,
- (2) A nucleic acid which that directs liver specific expression of an HCV immunogen wherein the nucleic acid comprises a liver specific enhancer wherein the liver specific enhancer is an apolipoprotein E enhancer (claims 45 and 46).

The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include

(i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/ Primary Examiner